

**Notice of Allowability**

Application No.

09/788,074

Applicant(s)

HOTAMISLIGIL, GOKHAN S.

Examiner

Mary M. Schmidt

Art Unit

1635

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 10/8/02 and Interview Summary attached.
2. ☒ The allowed claim(s) is/are 16,21-26 and 29-35.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☒ CORRECTED DRAWINGS must be submitted.
  - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☒ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>14</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____.              | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                       |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance      |
|  | 9 <input type="checkbox"/> Other _____.  |

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### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ingrid Beattie on 12/17/02. Permission was granted to deposit Account No. 50-0311, Reference No. 21509-044 for the addition of new independent claim 31 and new dependent claims 32-35.

2. The application has been amended as follows:

Claims 27 and 28 have been canceled.

Claim 16 (amended). A method of diagnosing a risk of developing insulin resistance comprising determining the level of human [or mouse] Mal1 transcript[s or polypeptide] comprising nucleotides 49-456 of SEQ ID NO:4 or mutants thereof or Mal 1 polypeptide comprising SEQ ID NO:3 or mutants thereof in a tissue sample, wherein an increase in the level of said transcript[s] or said polypeptide in said tissue compared to a normal control tissue indicates that said human [or mouse] is at risk of developing insulin resistance.

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Claim 31 (new). A method of diagnosing a risk of developing insulin resistance comprising determining the level of [human or] mouse Mal1 transcript[s or polypeptide] comprising from the group consisting of nucleotides 569-647 of SEQ ID NO:2, nucleotides 132-304 of SEQ ID NO:2, nucleotides 633-734 of SEQ ID NO:2, nucleotides 1226-1279 of SEQ ID NO:2, nucleotides 1-279 of SEQ ID NO:2 and mutants thereof, or Mal 1 polypeptide comprising SEQ ID NO:1 or mutants thereof in a tissue sample, wherein an increase in the level of said transcript[s] or said polypeptide in said tissue compared to a normal control tissue indicates that said [human or] mouse is at risk of developing insulin resistance.

In claim 29, line 1, "16" was replaced by --31--.

In claim 30, line 1, "16" was replaced by --31--.

Claim 32 (new). The method of claim 31, wherein said increase is 5% more than a normal control value.

Claim 33 (new). The method of claim 31, wherein said increase is 10% more than a normal control value.

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Claim 34 (new). The method of claim 31, wherein said increase is 20% more than a normal control value.

Claim 35 (new). The method of claim 31, wherein said increase is 50% more than a normal control value.

3. The following are the Examiner's Reasons for Allowance: The prior art did not teach nor fairly suggest the nexus between Mal1 expression and insulin resistance, nor the motivation to determine Mal1 levels for diagnosing a risk of developing insulin resistance. The specification as filed taught by way of example Mal1 deficient mice which showed increased insulin susceptibility. This nexus was not previously taught in the prior art. As such the allowed claims were found free of the prior art for diagnosing a risk of developing insulin resistance in a mammal via measuring the level of Mal1 in a tissue sample as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Inquiries relating to the status of this application may also be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt  
December 19, 2002